DIVISION OF BIOCHEMICAL TECHNOLOGY OF THE AMERICAN CHEMICAL SOCIETY

BIOT

The Best of BIOT Awards: October 11, 2017

Date	Area	Time	Presenter	Institution
Wednesday, October 11th	Biosimilars	12:00-12:30 PM	**John Marino**	National Institute of Standards and Technology
		Addressing the challenge of higher-order structure assessment of biologics with 2D NMR		
	Drug Product and Delivery	12:30-1:00 PM	**Aditya Tulsyan**	Amgen
		Learning from small data in the era of big data for real-time biopharmaceutical process monitoring		

Moderator: Roger Pak, BioTx Pharmaceutical R&D, Pfizer

Webinar registration can be made at ACS BIOT WebEx Webinars

"Addressing the challenge of higher-order structure assessment of biologics with 2D NMR"

John Marino, National Institute of Standards and Technology, Rockville, MD

The development of precision methods for the characterization of the higher order structure (HOS) of protein therapeutics, including monoclonal antibodies (mAbs), is a major priority in the pharmaceutical industry. Two-dimensional nuclear magnetic resonance (2D-NMR) heteronuclear correlation spectroscopy provides a robust approach for producing spectral 'fingerprints' of the HOS of a protein therapeutic that can be used for establishing consistency in drug manufacturing, assessing stability of drug formulations and for determining biosimilarity to an innovator reference product. Using a standard monoclonal antibody developed by NIST (NISTmAb), 2D NMR methods will be described that allow practical acquisition of ^{1}H-^{13}C and ^{1}H-^{15}N correlation spectra of intact mAb and protease-cleaved Fab and Fc fragments at natural isotopic abundance. Unbiased, statistical and chemometric tools that can be used to establish HOS comparability between mAb samples will also be presented.

“Learning from small data in the era of big data for real-time biopharmaceutical process monitoring”

Aditya Tulsyan, Amgen, Cambridge, MA, Greenwich, RI, Thousand Oaks, CA

Despite over two decades of research and advancement in the pharmaceutical batch process monitoring and control, existing methods are effective to use only for drug products with a long production history. Unlike other processes, the pharmaceutical processes pose a unique challenge to monitoring which we refer to as the Low-N problem. The Low-N problem represents a situation where the product has a limited production history (e.g., a new drug). Here N refers to the length of the production history or the number of historical campaigns for a drug product. From process monitoring perspective, the Low-N problem poses several challenges: (i) the data do not capture normal operations in entirety; (ii) model predictions are poor; and (iii) the control limits and control charts are not accurate. This talk will focus on a novel approach to perform smart real-time multivariate process monitoring under the Low-N scenario. Several case studies will also be discussed to elucidate the efficacy of the proposed method.